

EXHIBIT E

Christina Pramudji, MD

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT WEST VIRGINIA
CHARLESTON DIVISION

) Master File
IN RE: ETHICON, INC.,) No. 2:12-CV-02327
PELVIC REPAIR SYSTEM) MDL No. 2327
PRODUCTS LIABILITY)
LITIGATION) JOSEPH R. GOODWIN
_____) U.S. DISTRICT JUDGE
_____) _____
THIS DOCUMENT RELATES TO)
PLAINTIFFS:) CASE NO. 2:12-CV-02099
)
Tina Wilson, et al v.)
Ethicon, Inc., et al)

ORAL DEPOSITION OF
CHRISTINA PRAMUDJI, M.D.
JULY 7, 2016

<p style="text-align: right;">Page 74</p> <p>1 Obviously, we know you've read the literature</p> <p>2 on TVT. Does that literature speak to -- and I'm</p> <p>3 talking medical studies -- speak to the effect, if</p> <p>4 any, positive, negative, of TVT on quality of life, on</p> <p>5 emotional health, on relationships, on sexual function</p> <p>6 or dysfunction?</p> <p>7 MR. THOMPSON: Object to form.</p> <p>8 A. Yes, it does.</p> <p>9 Q. (By Mr. Snell) Is that -- is it your reading</p> <p>10 of that literature and knowledge base on those areas</p> <p>11 pertaining to psychiatric history and emotional health</p> <p>12 something that is part of your, you know, knowledge</p> <p>13 base?</p> <p>14 MR. THOMPSON: Object to form.</p> <p>15 A. Yes, I know that the literature and, of</p> <p>16 course, my own experience with the TVT is that it</p> <p>17 improves the quality of life of patients tremendously.</p> <p>18 Q. (By Mr. Snell) And do you in your general</p> <p>19 report identify studies and data supporting your</p> <p>20 opinions about its effect on quality of life,</p> <p>21 emotional health and things of that nature?</p> <p>22 MR. THOMPSON: Object to form.</p> <p>23 A. Yes.</p> <p>24 Q. (By Mr. Snell) In assessing TVT and its</p>	<p style="text-align: right;">Page 76</p> <p>1 emotional health one of the things assessed following</p> <p>2 treatment with TVT?</p> <p>3 A. Yes, No. 6 is emotional health, nervousness,</p> <p>4 depression, et cetera.</p> <p>5 Q. And so is it correct or not that in your</p> <p>6 field assessing emotional health is actually part and</p> <p>7 parcel of what you do in patients who receive TVT in</p> <p>8 assessing not just that one aspect, but their overall</p> <p>9 outcome?</p> <p>10 MR. THOMPSON: Object to form.</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. (By Mr. Snell) You were shown -- you were</p> <p>13 shown the IFU and asked if it contained certain words,</p> <p>14 a warning of certain words pertaining to erosion. Do</p> <p>15 you recollect that?</p> <p>16 A. Yes.</p> <p>17 Q. And I'm just going to ask you about the</p> <p>18 bladder erosion issue since -- Counsel, and we</p> <p>19 discussed and the other areas weren't really gone</p> <p>20 into, so I'm just going to stick with the erosion.</p> <p>21 On the very first page in the section titled</p> <p>22 Important, does this IFU for TVT state it is not a</p> <p>23 comprehensive reference to surgical technique for</p> <p>24 correcting SUI, device should be used by physicians</p>
<p style="text-align: right;">Page 75</p> <p>1 impact, in your opinion, it's positive, positive</p> <p>2 effects on quality of life, emotional health,</p> <p>3 relationships, et cetera. Do scientists and surgeons</p> <p>4 like yourself use standardized questionnaires to</p> <p>5 assess the impact on TVT on those various domains?</p> <p>6 MR. THOMPSON: Object to form.</p> <p>7 A. Yes, we do.</p> <p>8 Q. (By Mr. Snell) For example, I was just</p> <p>9 looking -- one of the papers you cite to of many in</p> <p>10 your general report is the Laura Kenyan 2014</p> <p>11 randomized control trial that looked at TVT. Do you</p> <p>12 recall that?</p> <p>13 A. Yes.</p> <p>14 Q. And they did, according to your report,</p> <p>15 numerous questionnaires that show significant</p> <p>16 improvements on quality of life, satisfaction, things</p> <p>17 of that nature. Do you recollect that?</p> <p>18 MR. THOMPSON: Object to form.</p> <p>19 A. Yes.</p> <p>20 Q. (By Mr. Snell) And one of those</p> <p>21 questionnaires, for example, was the incontinence</p> <p>22 impact questionnaire 7. And I don't have the ability</p> <p>23 to print out a copy, but I will represent and I will</p> <p>24 show you and Counsel. Of the seven questions, is</p>	<p style="text-align: right;">Page 77</p> <p>1 trained in the surgical treatment of stress urinary</p> <p>2 incontinence and specifically implanting the TVT</p> <p>3 device?</p> <p>4 A. Yes, that's what it says.</p> <p>5 Q. Okay. And would the risk of bladder</p> <p>6 perforation and bladder erosion, is that a risk that</p> <p>7 would be commonly known to the intended user, the</p> <p>8 physician trained in stress urinary incontinence and</p> <p>9 TVT?</p> <p>10 MR. THOMPSON: Object to form.</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. (By Mr. Snell) And when it states that the</p> <p>13 surgeon should specifically be trained in implanting</p> <p>14 TVT, if the surgeon undergoes that training, would he</p> <p>15 or she be made aware of the risk of bladder</p> <p>16 perforation or bladder erosion?</p> <p>17 MR. THOMPSON: Object to form.</p> <p>18 A. Yes.</p> <p>19 Q. (By Mr. Snell) Should the pelvic floor -- is</p> <p>20 the pelvic floor surgeon the intended user of the TVT</p> <p>21 device?</p> <p>22 A. Yes.</p> <p>23 Q. Would that intended user be expected to know</p> <p>24 of the risk of bladder perforation and bladder erosion</p>

<p style="text-align: right;">Page 78</p> <p>1 when using instruments passing by the bladder placing 2 a sling? 3 MR. THOMPSON: Object to form. 4 A. Yes. 5 Q. (By Mr. Snell) And you mentioned that that's 6 would be the literature and that can happen with 7 autologous slings. Is that what you were referencing? 8 MR. THOMPSON: Object. 9 A. Yes. 10 Q. (By Mr. Snell) Is your surgical training and 11 residency learning to do sling procedures, whether 12 synthetic or autologous or something else, is that 13 elemental risk that you learn about in your basic 14 training? 15 MR. THOMPSON: Object to form. 16 A. Yes, it is. 17 Q. (By Mr. Snell) Is that one of the reasons 18 why you believe that that would be a commonly known 19 risk to the intended user? 20 MR. THOMPSON: Object to form. 21 A. Yes. 22 Q. (By Mr. Snell) Under Instructions for Use, 23 we didn't really talk about this, but actually, I want 24 to go through some of this. It talks about the guide</p>	<p style="text-align: right;">Page 80</p> <p>1 erosion. 2 Q. And would that be understandable to the 3 intended user, a pelvic floor surgeon like yourself? 4 MR. THOMPSON: Object to form. 5 A. Yes. 6 Q. (By Mr. Snell) Is the intention on using the 7 guide, moving the bladder contralaterally, doing 8 cystoscopy, do those have -- are those done for a 9 reason? 10 A. Yes. Those are done to confirm that the 11 sling is not going through the bladder or too close to 12 the bladder mucosa. And that's implanted in the 13 bladder wall. It should be outside the bladder wall. 14 Q. Are those done to reduce the risk of 15 perforation and ultimately bladder erosion? 16 MR. THOMPSON: Object to form. 17 A. Yes. 18 Q. (By Mr. Snell) Would that be understandable 19 to a pelvic floor surgeon who is trained on stress 20 urinary incontinence surgery trained on the TVT 21 device? 22 MR. THOMPSON: Object to form. 23 A. Yes. 24 Q. (By Mr. Snell) Under Warnings and</p>
<p style="text-align: right;">Page 79</p> <p>1 and it says the purpose of the guide is to move the 2 bladder neck and urethra away from where the tip of 3 the needle will pass into the retropubic space. It 4 also says when you're using the guide you move the 5 bladder contralaterally to the side of the needle 6 passage. Do you see that? 7 A. Yes. 8 Q. It also says cystoscopy is performed to 9 confirm bladder integrity. Do you see that? 10 A. Yes. 11 Q. Do those three statements warn a pelvic floor 12 surgeon that, hey, there is a risk of bladder 13 perforation and bladder erosion? 14 MR. THOMPSON: Object to form. 15 A. Yes. 16 Q. (By Mr. Snell) When they talk about 17 confirming bladder integrity, what are they talking 18 about? 19 A. They're talking about confirming that the 20 trocar did not traverse through the bladder, that the 21 sling is not going through the bladder wall. 22 Q. If the sling is in the bladder wall, what is 23 that? 24 A. That's a perforation. It's a potential</p>	<p style="text-align: right;">Page 81</p> <p>1 Precautions it says: User should be familiar with 2 surgical technique for bladder neck suspensions. 3 Does that include the autologous slings that 4 you referenced earlier? 5 A. Yes, it does. 6 Q. Where there is a known risk of bladder 7 perforation and bladder erosion with those procedures? 8 A. Yes, it does. 9 Q. So a surgeon coming in to use a TVT, if he or 10 she was familiar with surgical technique of bladder 11 neck suspensions, would he or she, by way of their 12 basic training and knowledge, be aware of the risk of 13 bladder perforation and erosion? 14 MR. THOMPSON: Object to form. 15 A. Yes, they would. 16 Q. (By Mr. Snell) And he also goes to state 17 that those surgeons should be adequately trained in 18 implanting the TVT before employing the TVT. 19 Does training on the TVT warn and inform 20 surgeons about the risk of bladder perforation and 21 erosion? 22 MR. THOMPSON: Object to form. 23 A. Yes, it does. 24 Q. (By Mr. Snell) And did you, yourself,</p>

<p style="text-align: right;">Page 82</p> <p>1 perform professional education training on the TVT 2 systems? 3 A. Yes, I did. 4 Q. It says: The TVT procedure should be 5 performed with care to avoid the bladder. Attention 6 to local anatomy and proper passage of needles will 7 minimize risks. 8 What kind of risks are they talking about 9 there that you would understand as a pelvic floor 10 surgeon? 11 MR. THOMPSON: Object to form. 12 A. They're talking about bladder mesh erosion. 13 Q. (By Mr. Snell) Cystoscopy should be 14 performed to confirm bladder integrity or recognize a 15 bladder perforation. 16 Did I read that correctly? 17 A. Yes, you did. 18 Q. Does that warn a surgeon, a pelvic floor 19 surgeon, about the risk of perforation or erosion? 20 MR. THOMPSON: Object to form. 21 A. Yes, it does. 22 Q. (By Mr. Snell) And you point out also under 23 Adverse Reactions, it actually has the word "erosion." 24 MR. THOMPSON: Object the form.</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. (By Mr. Snell) And, for example, you cite 2 systematic reviews, which you've testified before, the 3 highest level of evidence. Those systematic reviews 4 for the retropubic TVT or the sling report rates of 5 dyspareunia at zero percent or sexual dysfunction is 6 zero percent. Do you recall putting that in your 7 general report? 8 MR. THOMPSON: Object to form. 9 A. Yes. 10 Q. (By Mr. Snell) Is that a basis for your 11 opinion that TVT did not cause the Plaintiff's 12 dyspareunia in this case? 13 A. Yes. 14 MR. THOMPSON: Object to form. 15 Q. (By Mr. Snell) And actually, compared to the 16 pubovaginal slings that Plaintiff's counsel asked you 17 about, is the risk of pain and sexual dysfunction with 18 TVT -- how does take compare? 19 A. It's actually less. 20 Q. And in your report where you talk about 21 reliable literature documenting significant 22 improvements in sexual function, is that a basis for 23 your opinions in this specific case? 24 MR. THOMPSON: Object to form.</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. (By Mr. Snell) Is that correct? 2 A. Yes, that's correct. 3 Q. Is the TVT IFU adequate to warn a pelvic 4 floor surgeon of the risk of bladder perforation and 5 bladder erosion, in your opinion? 6 MR. THOMPSON: Object to form. 7 A. Yes, it is. 8 Q. (By Mr. Snell) Does it actually, in numerous 9 places, actually warn about those risks? 10 MR. THOMPSON: Object to form. 11 A. Yes, it does. 12 Q. (By Mr. Snell) You were asked questions 13 about your opinion that the TVT does not -- did not 14 contribute to Ms. Wilson's dyspareunia. As support 15 for your opinion, I note in your case-specific report 16 that you incorporate your TVT general report. Is that 17 correct? 18 A. Yes. 19 Q. And so the literature and data and things at 20 Page 51, 52, 53, pertaining to TVT and its effect and 21 risk, if any, for dyspareunia, do you incorporate 22 those bases? 23 MR. THOMPSON: Object to form. 24 A. Yes.</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Yes. 2 Q. (By Mr. Snell) On the topic of urge 3 incontinence, the urgency, overactive bladder, is that 4 a topic you also cover in your general report? 5 A. Yes, it is. 6 Q. And for reference, I'm going to point to 7 Pages 49 through 51, for example. Is that -- does 8 that part of your general report talk about urgency, 9 overactive bladder, urge incontinence, and whether TVT 10 has been demonstrated to be a cause of those factors? 11 A. Yes, it -- 12 MR. THOMPSON: Object to form. 13 A. Yes, it does. 14 Q. (By Mr. Snell) You identify various factors 15 in Mrs. Wilson's case that you believe contributed to 16 her urgency and urge incontinence. Let me ask you 17 this: In your report at Page 49, general report, you 18 talk about mixed urinary incontinence. Can you tell 19 us what that is very briefly? 20 A. Yes, that's where the patient has two kinds 21 of incontinence. One is stress incontinence with 22 coughing, sneezing, exercise. And the second is the 23 urge incontinence where they have the feeling that 24 they've gotta go, gotta go. And so if they have both</p>

Christina Pramudji, MD

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
hereby certify that I have read the
foregoing pages, and that the same is
a correct transcription of the answers
given by me to the questions therein
propounded, except for the corrections or
changes in form or substance, if any,
noted in the attached Errata Sheet.

CHRISTINA PRAMUDJI, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires: _____

Notary Public

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THE STATE OF TEXAS:
COUNTY OF FT. BEND:

I, Tamara Vinson, a Certified Shorthand
Reporter and Notary Public in and for the State of
Texas, do hereby certify that the facts as stated by
me in the caption hereto are true; that the above and
foregoing answers of the witness, CHRISTINA PRAMUDJI,
M.D., to the interrogatories as indicated were made
before me by the said witness after being first duly
sworn to testify the truth, and same were reduced to
typewriting under my direction; that the above and
foregoing deposition as set forth in typewriting is a
full, true, and correct transcript of the proceedings
had at the time of taking of said deposition.

I further certify that I am not, in any
capacity, a regular employee of the party in whose
behalf this deposition is taken, nor in the regular
employ of his attorney; and I certify that I am not
interested in the cause, nor of kin or counsel to
either of the parties.

GIVEN UNDER MY HAND AND SEAL OF OFFICE, on
this, the ____ day of July, 2016.

Tamara Vinson, Texas CSR No. 3015
Expiration Date: 12-31-2016

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